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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,604	12/07/2001	Pablo D. Garcia	002441.00008	6543

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Emeryville, CA 94608-2916

EXAMINER
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HUMPHREY, LOUISE WANG ZHIYING

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/016,604

Applicant(s)

GARCIA ET AL.

Examiner

Louise Humphrey, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7,9,10 and 13-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,10 and 13-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date 1/21/2006

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 July 2006 has been entered.

The examiner of your application in the Patent and Trademark Office has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Louise Humphrey, Art Unit 1648.

***Response to Arguments***

Claims 1-7, 9, 10, and 13-15 are pending and under examination.

**Claim Rejections - 35 USC § 112, 1<sup>st</sup> ¶**

The rejection of claims 1-7, 9, 10, and 13-15 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement **is maintained** for reasons of record. Applicants' arguments are fully considered but are found unpersuasive.

In response to the argument that the identified 16 gene product isolates that are highly up-regulated in prostate cancer patients all share some degree of identity to

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members of the HML-2 subgroups of the HERV-K family, Applicants have not met the requirement for the Written Description in terms of the following factors: *partial structure, physical and/or chemical properties, and functional characteristics alone or coupled with a known or disclosed correlation between structure and function.*

M.P.E.P. § 2163 states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." M.P.E.P. § 2163 does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus.

Applicants have not disclosed the conserved structure in the identical regions or have compared structures between the 16 gene products and *all* of the HML-2 retroviral genes as claimed. In addition, as indicated in the previous Office Actions, one species of the claimed genus of HML-2, HERV-K 22q11, has a negative effect wherein higher EST expression is found in normal prostate tissue than in a cancerous prostate sample, so this gene product would not detect prostate cancer in the claimed method. Even Applicants themselves admit that the ordinary skilled artisan has to "determine which HML-2 retrovirus-encoded expression products are up-regulated in patients having prostate cancer, and which are not" on top of page 9 of the response filed on 21 July 2006. Therefore, Applicants are clearly not in possession of the entire broad genus of

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products to practice the claimed method. Likewise, Applicants are not in possession of the HML-2 retroviral products that are indicative of prostate cancer in a blood sample because the specification nowhere describes the partial or conserved structure of a blood sample that correlates with the function of indicating prostate cancer.

The rejection of claims 1-7, 9, 10, and 13-15 under 35 U.S.C. § 112, first paragraph, as being lack of enablement **is maintained** for reasons of record. Applicants' arguments are fully considered but are found unpersuasive.

Applicants argue that one skilled in the art could make and use the full scope of the claimed invention with only routine experimentation for detecting HML-2 retrovirus encoded expression products that are up-regulated by prostate cancer. The specification describes the identification of 16 PCR clones, obtained from a normalized cDNA library generated from one prostate cancer patient (spec. p.72), with sequence identity to HERV-K, which is not characterized to be associated with any disease (spec. p.77), let alone prostate cancer. These 16 clones were assayed among normal and tumorous prostate tissue from 13 patients for expression. Not all of the 16 clones detected at least 150% elevated expression of mRNA in the 13 patients. Apparently not all the HML-2 retroviral expression products can be used to detect prostate cancer. Finally, 13 patients cannot represent the whole population of prostate cancer patients.

Applicants made a leap in the dark without further evidence leading to the conclusion that an increased level of a HML-2 expression is correlated with the diagnosis of prostate cancer. The claimed method of prostate cancer diagnosis by

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detecting HML-2 expression product is highly unpredictable without studies of how the up-regulation of HML-2 is widely distributed among prostate tumors in both tissue and blood samples. Even though the claimed method of diagnosis is defined as to exclude distinguishing between prostate cancer and other types of cancer, there is still the uncertainty of whether HML-2 gene expression is indeed elevated in every prostate tumor sample. Aside from the lack of correlation, there is no guidance to determine whether the at least 150% increased level of HML-2 retroviral product in a blood sample is exclusively associated with prostate cancer and no other cancer. The specification does not provide guidance on the operative versus the inoperative HML-2 retroviral species. One skilled in the art is burdened with the undue experimentation of identifying every operative HML-2 retroviral expression products that correlate with prostate cancer in the prostate tissue and in the blood before the claimed method can be used.

***Remarks***

No claim is allowable.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP §714.02 and §2163.06.

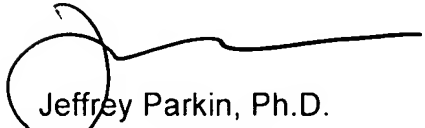
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**Contact Information**

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Jeffrey Parkin, Ph.D.  
Primary Examiner  
04 Aug 2006

*lvtt*  
8/9/2006